

## **REMARKS**

### **I. Introduction**

Applicants thank the Examiner for entry of the previous election of claims 1-3, 9, 11, 13, 15 and 26. Applicants again expressly reserve the right to pursue the non-elected claims in any related application, claiming priority to the present application, such as a continuation, divisional, or continuation-in-part application.

The two independent claims of the present application – claims 1 and 15 – have been amended. Both amended claims 1 and 15 now recite the limitation of a free-radical scavenger unit that exposes the blood in the circuit, after being exposed to nitric oxide gas, with a free-radical scavenger in a concentration sufficient to reduce the nitric oxide content in the blood. This limitation previously was found in dependent claims 13 (depending from claim 1) and 26 (depending from claim 15), that are herein canceled.

### **II. Information Disclosure Statement**

In connection with the Applicants' recently submitted supplemental Information Disclosure Statement (IDS), the Examiner stated "it is recommended that if any information that has been cited by Applicants in the previous disclosure statement is known to be material for patentability as defined by 37 CFR 1.56, Applicant should present a concise statement as to the relevance of that/those particular documents therein cited." (Office action at 3-4.)

Applicants currently are unaware if any of the information disclosed in the supplemental IDS is material to the patentability of the claims of the present application under 37 C.F.R. § 1.56. It is noted that U.S. Pat. Nos. 5,957,880 and 6,432,007 and PCT/CA99/01123 (WO 00/30659) are discussed in the specification of the present application, and are cited in the supplemental IDS.

The assignee of the present invention, Pulmonox Technologies Corp., is prosecuting a portfolio of patent applications generally related to medicinal uses of nitric oxide gas. Additionally, Pulmonox has partnered with one or more other companies in joint research regarding nitric oxide gas technologies. These partners also are prosecuting a portfolio of patent applications in connection with related technologies. The references disclosed in the supplemental IDS have been cited by examiners during the prosecution of other patent applications assigned to Pulmonox and/or Pulmonox's partners and in some instances also

have been referenced in the patent applications themselves or information disclosures submitted therewith. It is to avoid any semblance of impropriety in the form of withholding material information from the Examiner that Applicants have submitted this supplemental IDS. The size of the supplemental IDS reflects the size of the relevant patent portfolios of Pulmonox and its partners and Applicants' desire to forthrightly bring this information to the attention of the Examiner; Applicants in no way intend this IDS to cloak or bury a relevant reference.

III. Rejection under 35 U.S.C. § 103 over US 5,725,492 to Igo in view of Croen

"Claims 1-3, 11, 13, 15, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,725,492 to Igo in view of Croen." (Office action at 4.) The Examiner alleges that "Igo discloses a device and method for exposing a patient's blood to nitric oxide within an extracorporeal circuit." (*Id.*) "Igo fails to disclose that the NO exposure is sufficient to reduce pathogenic content in the blood," but "Croen teaches that NO exerts microbiostatic, microbiocidal, and antiviral effects on pathogens." (Office action at 5.) Further, in regards to claims 13 and 26, now canceled, the Examiner alleges that "Igo discloses that the device and method comprise the step of feeding the blood through a scavenger unit 67 to absorb residual NO." (*Id.*) Applicants respectfully traverse this rejection.

Independent claims 1 and 15, from which all the remaining claims in the present application depend, have been amended.

Amended claim 1 now reads, in relevant part: "(d) providing a free-radical scavenger unit that exposes the blood to free-radical scavengers after the blood is exposed to the nitric oxide." Likewise, amended claim 15 now reads, in relevant part: "a free-radical scavenger unit that exposes the blood in the circuit, after being exposed to nitric oxide gas, with a free-radical scavenger in a concentration sufficient to reduce the nitric oxide content in the blood."

Accordingly, amended claims 1 and 15 now recite the limitation previously found in dependent claims 13 and 26 – i.e. a free-radical scavenger unit that exposes the blood to free-radical scavengers.

Contrary to the assertion made in the Office action, the '492 patent to Igo does not disclose a free-radical scavenger unit that exposes blood to free-radical scavengers. Instead, the scavenger disclosed in Igo exposes excess carrier gas that is not absorbed into the blood to free-radical scavengers in order to remove residual nitric oxide gas from the carrier gas.

In this embodiment of '492 patent to Igo, a gas permeable membrane 60 is located within a conduit 62 of the blood circuit located immediately downstream from the reservoir 18. The gas permeable membrane 60 is elongated and tubular in form and is disposed longitudinally within conduit 62 adapted to come into contact with blood flowing through conduit 62. ... Due to the permeability of this membrane 60 to nitric oxide gas, the gas will diffuse through the membrane and dissolve in the blood plasma where it will come into contact with platelets. ... Coupled to the outlet of the membrane 60 is outlet tubing 61, which is connected to valve 63. ... From the valve 63 *the carrier gas and any residual nitric oxide gas is carried through tube 65 into container 67, which is filled with a scavenger liquid such as methylene blue.* The gas mixture is allowed to bubble up through the container containing the scavenger liquid. The scavenger liquid absorbs any residual nitric oxide so that the only gas that escapes into the atmosphere is the carrier gas.

(the '492 patent to Igo at 7:17-45, emphasis added.) It is apparent from the above quoted passage that the scavenger unit disclosed in Igo removes from the exhausted **carrier gas** any residual nitric oxide that was not dissolved into the blood plasma through the gas permeable membrane of the Igo device. In contrast, the scavenger unit recited in amended claims 1 and 15 of the present application treats **the blood** directly and removes nitric oxide gas from the blood, not from the carrier gas as in Igo.

The combination of the '492 patent to Igo and Croen therefore fails to disclose each and every limitation of amended claims 1 and 15. To establish a prima facie case of obviousness, the combined prior art references must teach or suggest all the claim limitations. See MPEP § 2142. Because Igo and Croen fail to teach the scavenger unit limitation, wherein the blood is treated and not a carrier gas, a prima facie case of obviousness has not been established for amended claims 1 and 15 and claims 2-3, 9, and 11, which depend from claim 1. Applicants respectfully request withdrawal of this rejection.

IV. Rejection under 35 U.S.C. § 103 over US 5,725,492 to Igo in view of Croen, further in view of McInnes et al.

“Claim 9 is rejected under rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,725,492 to Igo in view of Croen, further in view of McInnes et al.” (Office action at 5.) The Examiner alleges that “Igo and Croen disclose the method substantially as claimed by applicant (see rejection above) with the exception of targeting septicemia during the method. McInnes discloses that NO production appears to reduce septicemia in mice, suggesting that NO exposure might be a successful treatment for sepsis.” (Office action at 6.) Applicants respectfully traverse this rejection.

Applicants’ incorporate the arguments made previously in connection with Igo in view of Croen. Claim 1, from which claim 9 depends, has been amended to include an additional limitation that is not taught or suggested by either Igo or Croen, or otherwise obvious in light of Igo and Croen. Accordingly, claim 9, which incorporates the limitations of claim 1 from which it depends, also is not obvious in view of Igo and Croen combined with McInnes. Applicants respectfully request withdrawal of this rejection.

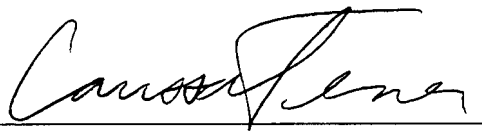
V. Conclusion

Applicants respectfully submit that the claims are in condition for allowance and request that the rejections be withdrawn and a Notice of Allowance be issued for all pending claims.

If the undersigned can be of any assistance to the Patent Office, a telephone call is respectfully requested. If any fees are required by this filing, the Commissioner is authorized to charge Sidley Austin LLP’s Deposit Account # 50-1597.

Respectfully Submitted

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